K133477

Traditional 510(k) Summary

FEB 10 2014

Synchro-Medical Toe Grip Device

Submitter:	Synchro Medical 21 rue des Merisiers FR-68920 Wettolsheim les Erlen
Contact Person	Danilo Campani President Phone: +33(0)3 89 23 75 64 Fax:+33(0)3 89 27 14 52 Email: dcampani@synchro-medical.com
Date Prepared	2/10/14
Device Class	Class II

Trade Name	TOEGRIP®.
Common Name	Synchro-Medical Toe Grip Device
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Classification Panel:	Orthopedic
Product Code	HTY
Predicate Devices	Inion OTPS Biodegradable Pin (K031712), Memometal Inc™ Smart Toe & X-Fuse (K070598) & New Deal K-Wire (K022599)
Previous Submissions	There are no previous submissions

Device Description	The TOEGRIP® device consists of a monobloc implant with three flexible prongs inserted intramedullary into each part of phalanx The prongs are linked by a T-shaped beam. The fixation concept is based on a press-fit contact due to its tapered shape and the sharp macrostructures once impacted. The TOEGRIP® device is intended for single use only, and is available in a range of 5 sizes with 3 possible degrees: 0°, 10° or 20°. The TOEGRIP® device is manufactured with material according to the ISO-10993, ZENIVA® PEEK. The feature design of the TOEGRIP® is substantially equivalent to the design features of other devices previously cleared for market.

Intended Use	The **TOEGRIP®** is intended for toes for general use in skeletally mature individuals undergoing surgery limited to interdigital fusion. The **TOEGRIP®** device is intended to be permanently implanted without any other additional device as an intramedullary bone fastener device for toes or fingers. The **TOEGRIP®** device is indicated for small bone reconstruction limited to interdigital fusion of toes in the following cases, listed in random order: • Rigid PIP joints deformities • Rigid hammertoes deformities • Claw toes deformities (PIP and DIP joints) • Revision hammertoes surgeries • Shortening osteotomies of the proximal phalanx
Materials:	The implant is manufactured from ASTM2026 implant grade Polyetheretherketone (PEEK) Solvay Zeniva ZA-500.

Statement of Technological Comparison	The purpose of this submission is to obtain market clearance for the proposed the Synchro-Medical Toe Grip Device. Synchro-Medical Toe Grip Device and its predicate devices have the similar indications for use, have a similar functionality. Both devices are manufactured using materials with a long history of use in orthopaedic implants.

Nonclinical Test Summary	The following tests were performed to demonstrate that the Synchro-Medical Toe Grip Device is substantially equivalent to other predicate devices. • Static Four-point Bending Test • Dynamic Four-point Bending Test The results of these studies showed that the Synchro-Medical Toe Grip Device met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Conclusion	The Synchro-Medical Toe Grip Device is substantially equivalent to its predicate devices. This conclusion is based upon the fact the Synchro-Medical Toe Grip Device and its predicate devices have the same indications for use and have a similar design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2014

Synchro Medical
% Mark F. Schenk Consulting
Mr. Mark F. Schenk
505 Berks Place
West Lawn, Pennsylvania 19609

Re: K133477
Trade/Device Name: Synchro-Medical Toe Grip Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: November 12, 2013
Received: November 12, 2013

Dear Mr. Schenk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K133477

Device Name: Synchro-Medical Toe Grip Device

Indications for Use:

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- Rigid PIP joints deformities
- Rigid hammertoes deformities
- Claw toes deformities (PIP and DIP joints)
- Revision hammertoes surgeries
- Shortening osteotomies of the proximal phalanx

Prescription Use X **AND/OR** **Over-the-counter** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth [illegible]rank -S

Division of Orthopedic Devices